REMARKS

I. STATUS OF CLAIMS

The Examiner has rejected Claims 4-11, 13-30, and 48-52 under 35 U.S.C. § 103(a), as being unpatentable over Stark et al. (US Patent No. 6,827,670), hereinafter, Stark) in view of Drazen (U.S. Published Patent Application No. 2002/0120471).

The Examiner also has rejected claim 12 under 35 U.S.C. § 103(a) as being unpatentable over Stark in view of Drazen and further in view of Smith (Smith, G. "Statistical Reasoning." Third Edition. Ch. 15, pgs. 619-667. Allyn and Bacon, a Division of Simon and Schuster, Inc., Needham Heights, MA. 1991).

II. REJECTION OF CLAIMS 4-11, 13-30, AND 48-52 UNDER 35 U.S.C. § 103(a)

A. Summary

The Examiner rejected claims 4-11, 13-30, and 48-52 under 35 U.S.C. § 103(a) in view of Stark and Drazen. The Applicants hereby submit an affidavit under 37 C.F.R. § 1.131 with a document titled 'Creation of training materials for a study configuration'. The Applicants believe that the submitted document will serve as a demonstration of fact that the Applicants possessed the whole invention as claimed or a species of a claim prior to the effective date of the Drazen reference used to assert obviousness. Therefore, the Applicants believe that the submitted document effectively antedates the Drazen reference, which renders the teachings of Drazen moot. In the following sections, the Applicants would like to bring the Examiner's attention to applicable rules and wish to demonstrate that the submitted reference evidently shows that the each claimed element was in possession of the Applicants on or prior to the effective date of Drazen reference.

B. Applicable Rules

MPEP §715.02 states that a Rule 1.131 affidavit or declaration must establish possession of either the whole invention claimed or something falling within the claim (such as a species of a claimed genus), in the sense that the claim as a whole reads on it (*In re Tanczyn*, 347 F.2d 830, 146

USPQ 298) (CCPA 1965). Also stated that the invention demonstrated in the Rule 131 affidavit does not have to match what is disclosed in the references; the critical demonstration is possession of either the overall inventive concept or a single claimed entity (e.g. a species) (*In re Wakefield*, 422 F.2d 897, 164 USPQ 636) (CCPA 1970). Lastly, the principal exception to the full possession requirement of a rule 131 affidavit is if the inventors can show, prior to the effective date of the latest reference, that full possession would have been obvious over their deficient rule 131 affidavit in view of the knowledge of one of skill in the art (*In re Spiller*, 500 F.2d 1170, 182 USPQ 614) (CCPA 1974).

C. Claims

As per claims 4-6, 8, 14, 24, 26, 48-52 and exemplary independent claim 16, the Applicants claimed "A method of predicting subject noncompliance during a current clinical trial, comprising the steps of:

providing historical subject compliance data from a previous clinical trial;

generating at least one predictive algorithm for predicting subject noncompliance by quantitative analysis of the historical subject compliance data;

translating the at least one predictive algorithm into at least one prediction rule for use during the current clinical trial;

obtaining subject compliance information during the current clinical trial;

comparing the subject compliance information to the at least one prediction rule to determine if action is needed; and

prompting action if the step of comparing indicates that action is needed."

One embodiment of the invention comprised of the claimed steps is illustrated in the submitted reference page 55-57. For example, the table on page 57 shows that numeric indications are employed as a function of noncompliance, which can be considered as a product of following the steps of the exemplary claim.

As per claims 9, 25, and exemplary claim 17, the Applicants claimed "wherein said step of providing includes providing historical protocol data and wherein said step of generating includes quantitative analysis of the historical protocol data." As shown in the table on page 57 of the submitted reference, the calculated results are resulted from quantitative analysis of the historical protocol data.

As per claims 10 and exemplary claim 18, the Applicants claimed "wherein the step of providing employs at least one database containing the historical protocol data." As shown in page 56 of the submitted reference, the invention utilizes a database of historical protocol data. In the specific example shown on page 56, it is illustrated that the embodiment has a capability of displaying such data in chronological order.

As per claims 7, 11, 15, 30 and exemplary claim 19, the Applicant claimed "wherein the step of obtaining includes the use of a portable electronic device capable of displaying information and receiving and storing input from a user." For example, as illustrated in page 27 of the submitted reference, one embodiment of the invention utilizes a portable electronic device. Also, the capability of the electronic device, such as receiving and storing input from a user, is illustrated in page 27-51.

As per claims 20 and 21-22, the Applicants claimed steps of creating an evaluability database adapted to store data related to subject compliance, providing access to the evaluability database to a sponsor to allow the sponsor to make a determination regarding a subject based on data from the evaluability database, and wherein the evaluability database is tailored to a condition affecting the subject. These elements can be found in the submitted reference. For example, the portable device has a capability to upload data to a database (page 40), the database can be accessed by the sponsor for monitoring purpose (page 55 under "tracking patients"), and the database can be tailored to subjects using patient feedback form (page 58).

As per claims 13 and exempary claim 23, the Applicants claimed "wherein the step of providing employs at least one database containing the historical subject compliance data." A database containing historical subject compliance data and various ways to display the data are shown in pages 52-66. For example, it is stated that "use patient data to help you make real-time decisions and interventions related to patient compliance" (page 52).

As per claims 27 and 28, the Applicants claimed "wherein the affirmative action includes reducing a number of occurrences of the step of obtaining subject compliance information" and "wherein the affirmative action includes increasing a number of occurrences of the step of obtaining subject compliance information". The portable device illustrated in the submitted reference demonstrates that the device has a capability of training mode, and therefore, either increase or reduce occurrences of the steps obtaining subject compliance information, if a need for such action is detected in the training session.

As per claim 29, the Applicants claimed "wherein the affirmative action includes giving a reward." Although the submitted reference does not explicitly state that giving a reward to a participant of a subject using portable electronic device for storing subject compliance information, various forms of participation reward in clinical trials is an inherently associated concept to a clinical trial. Rewarding participants of a clinical trial is also a part of standard practice of modern clinical trial. Therefore, the Applicants believe that claimed element of claim 29 was in our possession at the time of the submitted reference.

III. REJECTION OF CLAIMS 12 UNDER 35 U.S.C. § 103(a)

As per claim 12, the Applicants claimed "wherein the step of generating employs at least one of the group of multiple linear regression, discriminant function analysis, logistic regression, neural networks, classification trees and regression trees." The table in page 57 of the submitted reference demonstrates that statistical methods or other computing methods, such as the use of neural network are known in the art are employed for obtaining statistically calculated results of the claimed invention. For example, results are consolidated and treated by statistical method to

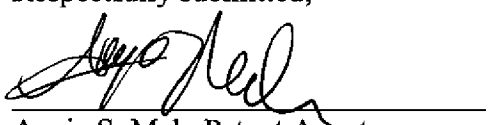
calculate the compliance average shown as a range from 1 to 10, with 1 being an indication of very serious compliance problems.

CONCLUSION

The Applicants believe that the submitted reference demonstrate that the Applicants possessed not just the portion allegedly taught by Drazen, but the whole invention as claimed or a species of a claim on or prior to the effective date of the submitted reference. Therefore, the Applicants respectfully request, based on the submitted affidavit under Rule 1.131 and accompanied reference, that the rejections on all claims be withdrawn.

Should the Examiner have any questions, the Examiner is encouraged to contact the undersigned patent agent at (202) 973-8870. The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. **23-2415** (Docket No. 31886-705.201).

Respectfully submitted,

Date: Aug. 18, 2008 By: 

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